


PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

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|---|--|---|-----------------------|
| Applicant's or agent's file reference 36433PC01 | FOR FURTHER ACTION | | See Form PCT/IPEA/416 |
| International application No. PCT/DK2005/000130 | International filing date (day/month/year) 25.02.2005 | Priority date (day/month/year) 26.02.2004 | |
| International Patent Classification (IPC) or national classification and IPC G01N33/497, C12Q1/24, G01N1/22 | | | |
| Applicant THOMSEN BIOSCIENCE A/S et al. | | | |
| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau) a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> | | | |
| <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p> | | | |
| Date of submission of the demand 22.12.2005 | | Date of completion of this report 20.03.2006 | |
| Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016 | | Authorized Officer Gunster, M Telephone No. +31 70 340-4412 | |



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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-39 as originally filed

Claims, Numbers

1-15 as originally filed

Drawings, Sheets

1/4-4/4 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
 - ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing *(specify)*:
 - ☐ any table(s) related to sequence listing *(specify)*:
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
 - ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing *(specify)*:
 - ☐ any table(s) related to sequence listing *(specify)*:

* If item 4 applies, some or all of these sheets may be marked "superseded."

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-------------|---------|
| Novelty (N) | Yes: Claims | 1-13,15 |
| | No: Claims | 14 |
| Inventive step (IS) | Yes: Claims | 1-12 |
| | No: Claims | 13-15 |
| Industrial applicability (IA) | Yes: Claims | 1-15 |
| | No: Claims | |

2. Citations and explanations (Rule 70.7):

see separate sheet

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Reference is made to the following documents:

- D1: WO 00/26405 A (MESOSYSTEMS TECHNOLOGY, INC) 11 May 2000;
- D2: US 2003/136205 A1 (TOTOKI SHINICHIRO) 24 July 2003;
- D3: US 6511831 B1 (BERNHAGEN JUERGEN ET AL) 28 January 2003;
- D4: US 6126800 A (CAILLAT ET AL) 3 October 2000.

NOVELTY

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 14 is not new in the sense of Article 33(2) PCT. Document D1 (figure 1) discloses a device comprising a chip site and an electrical interface for applying an alternating electric field (figures 2a and 2b; page 7, last paragraph - page 8, last paragraph) and a programmable unit (figure 1, (SPORE ID DISPLAY (32)) comprising software for providing a gaseous sample exposing the reaction mixture to an alternating electric field.

The subject-matter of claims 1-13 and 15 is new in the sense of Article 33(2) PCT as there is not mention in the prior art of methods that combine electrostatic collection of air borne biological particles with extraction of the biological material by alternating electrical fields and PCR detection, nor a chip comprising a sample chamber and electrodes on opposite sides of the chamber and a heating element to carry out such a method.

INVENTIVE STEP

The subject-matter of claims 1-12 comprises an inventive step in the sense of Article 33(3) PCT.

Document D1 (page 4, line 33 - page 7, line 30; figure 1) which is considered to represent the most relevant state of the art to the subject-matter of claim 1, discloses a method for detecting biological particles by:

- a) collecting the biological particles from the air using an impactor (page 5,

- paragraph 3);
- b) extracting the biological material from the biological particle by applying an alternating electrical field (figure 2);
- c) performing PCR (page 7, paragraph 3); and
- d) measuring the presence of the amplified target nucleic acid (page 7, paragraph 3).

The subject-matter of independent claim 1 differs from the disclosure of D1 in that

- i) an electrical precipitator is used to collect the biological particles;
- ii) the particles are contacted with a liquid;
- iii) the lysis takes place in the sample chamber;
- iv) sample chamber is smaller, which results in a higher concentration of the sample.

The problem to be solved by the present invention may therefore be regarded as the provision of an alternative method for detecting biological particles from air using PCR and alternating field extraction.

Even though it might be obvious for the skilled person to replace the impacter with a smaller electrical precipitator such as disclosed in D2, there is no incentive in the prior art to perform the lysis in the sample chamber itself. Thus the subject-matter of claim 1 is not obvious to the skilled person.

Therefore, the solution proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT).

Consequently, the subject-matter of dependent claims 2-12 is also inventive (Article 33(3) PCT).

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 13-15 does not involve an inventive step in the sense of Article 33(3)PCT.

Document D3 (figure 5; example 5; column 15, lines 38-41), which is considered to represent the most relevant state of the art, discloses a sample chamber comprising a chip and two electrodes on either side of the chamber and having two openings in fluid connection with the air and for a device, the bottom electrodes are also detection electrodes (column 14, line 55).

From this, the subject-matter of independent claim 13 differs in that the sample chamber

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comprises a heating element and a temperature sensing element.

The problem to be solved by the present invention may be regarded as providing a sample chamber suitable for extraction and PCR analysis.

Document D3 teaches that the sample chamber could also be used for performing (preferably isothermic) PCR. Therefore the skilled person would be prompted to incorporate the heating electrode and temperature sensing element such as disclosed in D4 (figure 5, see reference numbers 264 and 266; column 4, lines 19-26; column 5, lines 31-39) into the sample chamber of D3.

The solution to this problem proposed in claim 13 of the present application is therefore not considered as involving an inventive step (Article 33(3) PCT).

It should be noted that the sample chambers of D3 and D4 are empty before use and at that stage comprise air, which is a gaseous sample. Thus, the fact that the chip comprising a sample chamber according to claim 13 comprises a gaseous sample is trivial and is of no consequence when assessing inventive step.

Dependent claim 15 does not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step (Article 33(3) PCT).

INDUSTRIAL APPLICABILITY

The subject-matter of claims 1-15 is industrially applicable in the field of biological particle detection.